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| **Spirometry - Adult** |
| **Protocol Id:** | 91601 |
| **Description of Protocol** | A spirometric test requires that the subject take a full, deep breath and then exhale as forcefully as possible into a handheld portable spirometer. The subject’s effort is called the forced expiratory maneuver and most commonly measures the amount and speed of air that is exhaled. The total amount (volume) of air exhaled is called the forced vital capacity (FVC). The amount of air exhaled in 1 second is called the forced expiratory volume in 1 second (FEV1). Although handheld spirometers are commonly used in clinical research studies, the same results can be obtained from more-sophisticated floor-mounted devices, which are typically available in a respiratory function testing laboratory. |
| **Specific Instructions** | Numerous instructions are embedded in the protocol and in Table 1 of the protocol. This protocol is mainly for adults. The Spirometry - Preschool and Child protocol uses animated computer software and visual cues, which are necessary for young children.  |
| **Protocol:** | Full protocol is available in the Spirometry Standards PDF, available at: [ATS ERS Spirometry Standards (2005)](https://www.phenxtoolkit.org/toolkit_content/supplemental_info/respiratory/additional_info/ATS_ERS_Spirometry_Standards_2005.pdf)ID (patient identification):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Patient name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Data type (SP followed by E=expiratory or I=Inspiratory, followed by S=single or B=best curve):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Barometric pressure (mmHg) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Temperature (°C) used in BTPS calculation:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Relative humidity (%):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_FVC quality attribute (A, B, C, D or F) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_FEV1 quality attribute (A, B, C, D or F) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Effort attribute (A, B, C, D or F) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Interpretation code (see ATS interpretation scheme) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Deleted manoeuvre (Y or N) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Acceptable manoeuvre (Y or N) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Technician quality control code (A, B, C, D or F) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Computer quality code (A, B, C, D or F) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Plateau achieved (Y or N) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Review (N or R for ‘‘needs review’’ or ‘‘was reviewed’’) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of review (DD/MM/YYYY) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reviewer initials:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_BTPS factor (x.xxx) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Spirometer manufacturer:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Spirometer model:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Spirometer serial number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Spirometer type:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Testing facility name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_City:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_State/region:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Zip/post code:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Country:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Calibration date (DD/MM/YYYY) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Calibration time (HH:MM) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Calibration result (P or F for ‘‘passed’’ or ‘‘failed’’) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date (DD/MM/YYYY) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Time (HH:MM) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Technician ID (technician identification code or initials) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Manoeuvre number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Age (integer years) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Height (cm) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Weight (kg) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Sex (M or F) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Race (2-character race code) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of birth (DD/MM/YYYY) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reference values source (first author surname and date of publication, e.g.‘‘Knudson 1983’’) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reference values correction factor (x.xx, 1.00 for no correction) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Testing position (standing, sitting or supine) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Test type (pre-, post-, bronchodilator, methacholine concentration or dose) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_FVC (mL) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Extrapolated volume (mL) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_FEV1 (mL) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_FEV6 (mL) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PEF (mL / s) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_FEF25–75% (mL / s) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_VC (mL) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Forced expiratory time (s) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Time to PEF (ms) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Predicted FVC (mL) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Predicted FEV1 (mL) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Predicted FEV6 (mL) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Predicted FEV1/FVC% (xxx.x%):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Predicted FEV1/FEV6% (xxx.x%):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Comments text:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Original sampling interval (ms) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 1 or FEF25%:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 2 or FEF50%:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 3 or FEF75%:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 4 or FEF90%:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 5:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 6:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 7:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 8:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 9:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Blank 10:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Number of data points:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Flow data points (mL/s; variable number contained in number of data points) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Selection Rationale** | Spirometry is invaluable as a screening test of general respiratory health. This protocol is the international standard supported by both the American Thoracic Society and the European Respiratory Society. The selected protocol is well-established over many years and serves as the unambiguous standard for lung function assessment in clinical research studies. |
| **Source** | Miller, M. R., Hankinson, J., Brusasco, V., Burgos, F., Casaburi, R., Coates, A., . . . Wanger, J. (2005). Standardisation of spirometry. Series “ATS/ERS task force: Standardisation of lung function testing.” *European Respiratory Journal, 26*(2), 330-331. |
| **Language** | English |
| **Participant** | Adults |
| **Personnel and Training Required** | Technician trained in conducting Pulmonary Function Tests (PFTs) with a spirometer |
| **Equipment Needs** | The primary instrument used in pulmonary function testing is the spirometer. |
| **Standards:** |

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| **Standard** | **Name** | **ID** | **Source** |
| Common Data Element (CDE) | Person Pulmonary Function Test Measurement Text | 2970229 | [CDE Browser](https://cdebrowser.nci.nih.gov/CDEBrowser/search?elementDetails=9&FirstTimer=0&PageId=ElementDetailsGroup&publicId=2970229&version=1.0) |
| Logical Observation Identifiers Names and Codes (LOINC) | Resp spirometry proto | 62639-0 | [LOINC](http://s.details.loinc.org/LOINC/62639-0.html?sections=Web) |

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| **General references** | Andreeva, E., Pokhaznikova, M., Lebedev, A., Moiseeva, I., Kozlov, A., Kuznetsova, O., & Degryse, J. (2015). The RESPECT study: RESearch on the PrEvalence and the diagnosis of COPD and its Tobacco-related etiology: a study protocol. *BMC Public Health,* *15*(1), 831.Berntsen, S., Stølevik, S. B., Mowinckel, P., Nystad, W., & Stensrud, T. (2016). Lung function monitoring; A randomized agreement study. *Open Respiratory Medicine Journal*, *10*, 51-57. Centers for Disease Control and Prevention (CDC). National Health and Nutrition Examination Survey (NHANES) 2007-2008. Respiratory Health Spirometry Procedures Manual. |
| **Protocol Type** | Physical Examination |
| **Derived Variables** | None |
| **Requirements** |

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| **Requirement Category** | **Required** |
| Major equipmentThis measure requires a specialized measurement device that may not be readily available in every setting where genome wide association studies are being conducted. Examples of specialized equipment are DEXA, Echocardiography, and Spirometry | No |
| Specialized training This measure requires staff training in the protocol methodology and/or in the conduct of the data analysis. | Yes |
| Specialized requirements for biospecimen collectionThis protocol requires that blood, urine, etc. be collected from the study participants. | No |
| Average time of greater than 15 minutes in an unaffected individualAverage time of greater than 15 minutes in an unaffected individual | No |

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| **Process and Review:** | [Expert Review Panel #6](http://phenx.org/node/118) (ERP 6) reviewed the measures in the Respiratory domain. Guidance from the ERP 6 includes the following:• No significant changes to measureBack-compatible: no changes to the Data Dictionary Previous version in Toolkit archive ([link](https://www.phenxtoolkit.org/index.php?pageLink=browse.archive.protocols&id=90000)) |